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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,958	03/10/2004	Stephen Brushey	DB000841-007	4864

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EXAMINER	
BOUCHELLE, LAURA A	
ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,958	BRUSHEY, STEPHEN	
	Examiner	Art Unit	
	LAURA A. BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 60-75* is/are pending in the application.

4a) Of the above claim(s) *60-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/8/09 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "said end cap having an outer diameter no greater than an inner diameter of said tube" may be new matter. Applicant points to a passage in the specification for support. However, upon close inspection, the passage describes the components that form the device as shown in Fig. 4A. As can be seen in Fig. 4A, the end cap 31 appears to extend to the outer diameter of the tubular member 32. Applicant asserts that the insertion of the end cap into the tube and positioning it such that the end cap extends out of the distal tip requires that the outer

diameter of the cap is no larger than the inner diameter of the tube. The examiner does not agree with this reasoning. First, the passage does not disclose that the end cap is inserted through the tube from the proximal end and out the distal end. The reinforcement member and the end cap may be inserted starting at the distal end, the reinforcement member being threaded through the tube until the end cap is in place at the distal end. In other words, the end cap never passes through the tube. Second, if the device is assembled as applicant argues, the tube is described as being a flexible tube so the tube may expand as the end cap is passing though.

4. If Applicant believes that this rejection is in error, please provide further support for this position.

Response to Amendment

5. The declaration under 37 CFR 1.132 filed 9/8/09 is insufficient to overcome the rejection of claim 1 based upon U.S.C 103(a) as set forth in the last Office action because: The declaration argues that "replacing" the distal tip shown in Fig. 10A of Hafer with the distal tip 72 shown in Fig. 3 would be inadvisable because the distal tip of Fig. 72 does not have enough surface area to provide a sufficient bond between the tubular member and the distal tip. While this argument may be valid, it misses the heart of the rejection. The combination being made in the instant rejection is not a matter of substituting the distal tip shown in Fig. 10 for the distal tip shown in Fig. 3. Instead, the rejection relies upon using the teaching of Fig. 3 that the distal tip may have a dome shape, and applying that shape to the distal tip of Fig. 10A. In other words, the device shown in Fig. 10A remains the same, including the cylinder portion 156 which is connected to the distal end of the tube, but for the shape of the distal most portion which is

changed from the flattened shape shown in Fig. 10A to the rounded dome shape shown in Fig. 3. Therefore, the argument that the contacting surface area is too small to be functional is not relevant.

Election/Restrictions

6. Newly submitted claims 60-75 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 60 corresponds to a species that was not elected based on the restriction requirement mailed 7/22/08. Furthermore, the claim now depends from claim 1, thereby forming an embodiment that was not previously considered.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 60-75 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

7.

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1, 4, 6-8, 11, 16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hafer et al (US 7386341). Hafer discloses a catheter system comprising a flexible cylindrical tube 56 terminating in an open distal tip and having a plurality of openings 162, a conductive cap 150 closing the open distal tip of the tube, a flexible conductive member 57 attached at one end to the conductive cap and running the length of the tube (Col. 12, lines 8-22, 54-56). See Figs. 10A-C. As shown in Fig. 10C, the tube has at least 4 openings 162 that are off set from each other at least 180 degrees and arranged in at least 2 rows. The tube is formed of a sterilizable thermoplastic material (col. 6, lines 36-37).

11. Regarding the limitation that the end cap has an outer diameter no greater that an inner diameter of the tube, the examiner believes that Hafer shows this feature. This limitation is interpreted to mean than the end cap must have *an* outer diameter, meaning any one of many, that is no larger than the internal diameter of the tube. In the instant case, the end cap of Hafer includes multiple outer diameters, and at least one of them is no larger than the inner diameter of the tube. Fig. 10A is reproduced below for clarity. The indicated portion of the end cap has an outer diameter no larger than the inner diameter of the tube.

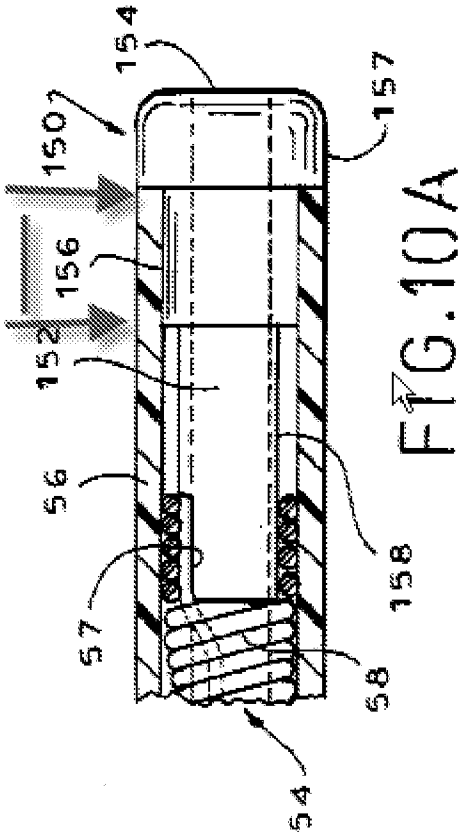

FIG. 10A

12. The end cap 150, called a "slug" by Hafer, may be interpreted as being dome shaped. Alternatively, it would have been obvious to form the slug in the same shape as the conductive tip 72 shown in fig. 3 of Hafer for example. The Federal Circuit has found that it is obvious to combine embodiments in a single prior art reference stating, "Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness." (Boston Scientific v. Cordis, Fed. Cir. 2009). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the embodiments to modify the end cap shown in Fig. 10 to have a dome shape as shown in fig. 3 since the combination is a predictable variation.

Claim Rejections - 35 USC § 103

13. Claims 2, 3, 5, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafer in view of Massengale (US 2002/0052576). Claims 2, 3, 5, 9 call for dimensions of the device. Hafer is silent as to the dimensions, only disclosing that the tube is small enough to be inserted through a needle. Massengale discloses a fluid delivery catheter comprising a catheter having a distal tip comprising an end cap 348, and a plurality of openings 364, 372, 356, 404. The catheter has an inner diameter of 0.019 inches, and an outer diameter of 20 gauge (Page 12, paragraph 0133). The length of the diffusion area may be any desired length (page 12, paragraph 0137), but is preferably about0.5 inches to 20 inches (page 13, paragraph 0140). The adjacent openings may be spaced between 0.125 inches and 0.25 inches (page 13, paragraph 0140). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Hafer to have the dimensions as taught by Massengale because both devices are used to deliver fluids to the body and so the device of Hafer would perform equally well with the dimensions of Massengale.

14. Claim 10, 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Beisel (US 5947940). Claim 10 differs from the teachings above in calling for a window for visualizing flashback. Beisel teaches an epidural catheter similar to that of Hafer but further including a window for visualizing flashback (Col. 3, lines 40-42). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Hafer to include a flashback window as taught by Beisel to assist the user in proper placement of the device.

15. Hafer is similarly silent as to the specific material of the tube. Massengale discloses that the catheter may be formed of a sterilizable plastic such as polyamide (page 12, paragraph 0133). It would have been obvious to one of ordinary skill in the art at the time of invention to form the tube of Hafer from the claimed materials as taught by Massengale because it is known to use such materials in medical devices for their biocompatibility, non-reactiveness, and ability to be sterilized.

16. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hafer in view of Massengale as applied to claim 11 above, and further in view of Brushey (US 6676643). Claim 14 differs from the teachings above in calling for the device to be formed of polyurethane and at least one siloxane. Brushey teaches that a device may be formed of polyurethane and at least one siloxane. Siloxane, commonly called silicone rubber, is well known in the medical arts for its flexibility and biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to form the device of Hafer in view of Massengale of polyurethane and siloxane as taught by Brushey because both materials are commonly used for their flexibility and biocompatibility.

17. Claims 15, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafer. Regarding claim 15, Hafer is silent as to the specific material of the conductive material. Hafer discloses that the flexible element and the end cap are formed of a conductive metal. It is well known in the art to use stainless steel in electrical stimulation devices because it is biocompatible and nonreactive. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the conductive flexible element from stainless steel.

18. Regarding claim 17, Hafer fails to disclose the dimensions of the wire. Where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04.

Response to Arguments

19. Applicant's arguments filed 9/8/09 have been fully considered but they are not persuasive. The declaration submitted 9/8/09 has been considered and was not persuasive. See the response above.

20. Applicant argues that Hafer fails to teach an end cap having a diameter no greater than the inner diameter of the tube. This limitation is interpreted to mean than the end cap must have *an* outer diameter, meaning any one of many, that is no larger than the internal diameter of the tube. In the instant case, the end cap of Hafer includes multiple outer diameters, and at least one of them (portion 156) is no larger than the inner diameter of the tube. For the full response to this limitation see the rejection of claim 1 above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
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